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30 ROCKEFELLER PLAZA
44TH FLOOR
NEW YORK, NY 10112-4498

EXAMINER	
ANDERSON, JAMES D	
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1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,272	MODAK ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-17) in the reply filed on 2/2/2007 is acknowledged. The traversal is on the ground(s) that the methods of Group III would require the same search as that for the compositions of Group I. As such, Applicants assert that it would not present an undue burden to search the groups together. This is not found persuasive because the compositions recited in the claims of Group I can be used for a materially different purpose than that recited in the claims of Group III. For example, as noted in the Restriction Requirement, the compositions of Group I could be used as anti-viral lubricants to effectuate the inactivation of HIV-1 or other viruses implicated in the spread of sexually transmitted diseases (U.S. Patent No. 5,940,477) (cited by Applicants).

Applicant's election of the following species: glucam P-20 (emollient), cationic hydroxyl ethyl cellulose (gelling or thickening agent), dimethiconal fluid in dimethicone (silicone polymer), benzalkonium chloride (antimicrobial agent), surfactant and farnesol (compound of claim 16) in the reply filed on 2/2/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 18-30 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/2/2007.

Status of the Claims

Claims 1-30 are currently pending and are the subject of this Office Action. Claims 18-30 are withdrawn from consideration. Claims 1-17 are presently under examination.

Priority

The present application is a continuation-in-part of International Patent Application PCT/US03/03896 filed February 27, 2003, which claimed priority to provisional United States Patent Application Serial Number 60/355,549 filed February 7, 2002.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed 11/5/2004, 4/10/2006 and 3/8/2007. Examiner has considered the references cited therein to the extent that each is a proper citation. Please see attached USPTO Form 1449.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "the water-soluble, organic zinc salts" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "...the water-soluble, organic salts of zinc..." would overcome this rejection.

Claim 17 recites a composition of claim 1 further comprising a synergistic amount of chlorhexidine gluconate, benzalkonium chloride and incroquat. It is not clear for what the amount is synergistic. Synergistic implies that some "effect" is more than that which would be expected from each component individually. However, the claims are drawn to compositions. As such, it is not clear what the "synergistic amount" is effective for.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claim recites, "one or more natural or synthetic chemicals". Said chemicals are selected from the group consisting of a monoterpene hydrocarbon, a sesquiterpene hydrocarbon, a monoterpene alcohol, a sesquiterpene alcohol, an ester, an ether, an aldehyde, a ketone, an oxide, almond oil, ylang-ylang oil, neroli oil, sandalwood oil, frankincense oil, peppermint oil,

lavender oil, jasmine absolute, geranium oil bourbon, spearmint oil, clove oil, lemongrass oil, cedarwood oil, balsam oils, tangerine oil, l-citronellol, α-amylcinnamaldehyde, lyral, geraniol, famesol, hydroxycitronellal, isoeugenol, eugenol, eucalypus oil, eucalyptol, lemon oil, linalool and citral. The specification discloses example essential oils and fragrances (*e.g.*, page 19, ¶[0043]), which include the instantly claimed oils. However, the specification does not disclose any other monoterpene hydrocarbons, sesquiterpene hydrocarbons, monoterpene alcohols, sesquiterpene alcohols, esters, ethers, aldehydes, ketones or oxides as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is a recitation of broad chemical classes (*e.g.* "a ketone"). Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to the DNA arts, the findings in *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and *Enzo Biochem, Inc. v. Gen-Probe Inc.* are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in *Lilly*. The court stated that, "[A] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the

claimed subject matter sufficient to distinguish it from other materials. " *Lilly* at 1567, 43 USPQ2d at 1405. The court also stated that:

> "[A] generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." *Id.* at 1568, 43 USPQ2d at 1406.

The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.*

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *Id.*

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The *Enzo* court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." *Id.* at 1324, 63 USPQ2d at 1613 (emphasis added, bracketed material in original).

While the inventions at issue in *Lilly* and *Enzo* were DNA constructs *per se*, the holdings of those cases are also applicable to claims such as those at issue here (which are drawn to very broad chemical classes). The instant specification may provide an adequate written description of the claimed genera (*e.g.* ketones or sequiterpene hydrocarbons), per *Lilly*, by structurally describing representative compounds (*e.g.*, specific ketones, specific sequiterpene hydrocarbons, etc.), or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per *Enzo*, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe ketones, oxides, ethers, aldehydes, etc. useful in the claimed invention in a manner that satisfies either the *Lilly* or *Enzo* standards. Although the specification discloses and claims several specific essential oils and fragrances, this does not provide a description of the broadly claimed chemical classes that would satisfy the standard set out in *Enzo* because the specification provides no functional characteristics coupled to structural features. Further, the specification also fails to describe the claimed chemical classes by the test set out in *Lilly* because the specification describes only a few essential oils and fragrances (all of which have different structures and are composed of different chemicals). Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of monoterpene hydrocarbons, sesquiterpene hydrocarbons, monoterpene alcohols, sesquiterpene alcohols, esters, ethers, aldehydes, ketones or oxides that is required to practice the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Modak *et al.* (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) (cited by Applicants in IDS filed 11/5/2004).

The instant claims are drawn to a composition comprising two or more water-soluble, organic salts of zinc, water, ethanol and one or more agents selected from the group consisting of gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents and emollients.

Modak *et al.* teach the use of organic salts of zinc in topical formulations (Abstract). Organic salts of zinc include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laurate, zinc stearate, zinc lactate and zinc propionate (col. 1, lines 56-60). These are the same organic zinc salts recited in instant claim 2. The organic salts of zinc may be

comprised in a cream base, which may be hydrophilic or hydrophobic (col. 2, lines 8-9). Said cream bases are known to include water, dimethicone, glycerin and other excipients (*id.* at lines 10-26). The concentration of organic salts of zinc may vary from between 1 to 15% and in a particular embodiment, may comprise 0.1 to 1% zinc salicylate (*id.* at lines 27-30 and lines 36-45)). This teaches the limitation recited in claim 1. Further, in addition to zinc salicylate, the compositions may comprise "one or more other organic salts of zinc, thus teaching the limitation "two or more" as recited in instant claim 1 (*id.* at lines 30-31). With respect to the amounts of water and emollients recited in the instant claims, if the compositions taught in Modak et al. comprise about 1 to 15% organic zinc salt in a cream base, the remaining percentage must be comprised of water and emollients.

Claims 1-13 and 15-16 are rejected under 35 U.S.C. § 102(e)(2) as being anticipated by Dodd *et al.* (U.S. Patent No. 6,344,218; Issued Feb. 5, 2002; Filed May 27, 1999) (newly cited art).

The instant claims are drawn to a composition comprising two or more water-soluble, organic salts of zinc, water, ethanol and one or more agents selected from the group consisting of gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents and emollients.

Dodd *et al.* teach aqueous compositions comprising an odor-controlling agent and select sanitizing agents (Abstract). A preferred composition comprises an effective amount of an odor controlling agent, from 40% to 99% of an alcohol antiseptic, from 0 to 10% of a water-soluble metallic salt, from 0 to 10% of a thickener, from 0 to 10% of an emollient, from 0 to 1%

of perfume and water (col. 2, lines 24-33). Water-soluble metallic salts are taught to be useful as odor-controlling agents (col. 3, lines 45-46). Specifically, preferred metallic salts include zinc gluconate, zinc lactate and zinc salicylate (col. 6, lines 10-12). The metallic salts are present in the compositions in amounts ranging from 0.01% to 10%, preferably 0.3% to 5% (*id.* at lines 17-25). These salts and amounts anticipate the limitations recited in instant claims 1 and 2. The compositions taught in Dodd *et al.* comprise between 5% and 70% water, thus teaching the limitations of instant claim 3 (col. 10, lines 32-35). Optionally, but preferably, emollients can be added to the compositions, including silicone oils, branched hydrocarbons, petrolatum, dimethicones and polyethylene glycol (*id.* at lines 40-67). The emollients comprise from 0.5% to 50%, more preferably 0.5% to 10% by weight of the compositions, thus teaching the limitations of claims 4 and 5 (*id.* at lines 63-66). Optionally, but preferably, thickeners can be added to the compositions of the invention (col. 11, lines 1-2). Said thickeners include polymeric materials (*e.g.* starch), cellulose ethers and cationic celluloses (*id.* at lines 23-67). The thickeners comprise from 0.01% to 10%, preferably 0.1% to 5% by weight of the compositions, thus teaching the limitations of claims 6 and 7 (col. 12, lines 8-14). Surfactants, including silicone surfactants (*e.g.* dimethyl polysiloxane hydrophobic polymers) are taught at column 16, line 65 to column 19, line 45. The amounts of surfactants range from 0% to 20%, most preferably 0.25% to 2.5% (col. 19, lines 46-49). The reference thus teaches the limitations of claims 8-9, 12-13 and 15. Antimicrobial agents, including benzalkonium chloride and chlorhexidine salts are taught at column 8, lines 8-25 and 33-35. When chlorhexidine and its salts are used, they are present in amounts ranging from 0.001% to 0.4% (col. 8, lines 38-42). This teaches the limitations of instant claims 10 and 11. Antioxidants are taught at column 24,

line 45, thus teaching the limitations of claims 12-13. The additional optional ingredients taught at column 24, lines 35-60 encompass the natural or synthetic chemicals recited in instant claim 16. The examples shown at column 26 to column 30 include ethanol, thus teaching a further limitation of instant claim 1.

The reference thus teaches the limitations of instant claims 1-13 and 15-16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

The instant claims are drawn to a composition comprising two or more water-soluble, organic salts of zinc, water, ethanol and one or more agents selected from the group consisting of gelling agents, thickening agents, hydrophilic or hydrophobic polymers, emulsifying agents and emollients.

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Modak *et al.* (U.S. Patent No. 5,985,918; Issued Nov. 16, 1999) (cited by Applicants in IDS filed 11/5/2004).

Modak *et al.* disclose the use of organic salts of zinc in topical formulations (Abstract). Organic salts of zinc include zinc salicylate, zinc tannate, zinc gluconate, zinc undecylenate, zinc valerate, zinc laurate, zinc stearate, zinc lactate and zinc propionate (col. 1, lines 56-60). These are the same organic zinc salts recited in instant claim 2. The organic salts of zinc may be comprised in a cream base, which may be hydrophilic or hydrophobic (col. 2, lines 8-9). Said cream bases are known to include water, dimethicone, glycerin and other excipients (*id.* at lines 10-26). The concentration of organic salts of zinc may vary from between 1 to 15% and in a particular embodiment, may comprise 0.1 to 1% zinc salicylate (*id.* at lines 27-30 and lines 36-45)). This teaches the limitation recited in claim 1. Further, in addition to zinc salicylate, the compositions may comprise "one or more other organic salts of zinc, thus teaching the limitation "two or more" as recited in instant claim 1 (*id.* at lines 30-31).

The instantly claimed compositions comprising two or more organic zinc salts would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, Modak *et al.* disclose a topical composition comprising from 1 to 15% organic zinc salt in a hydrophilic or hydrophobic cream base. It is well known in the art that cream bases comprise gelling agents, thickening agents, polymers, emulsifying agents and/or emollients. As such, there is nothing non-obvious about the

instantly claimed compositions in view of the Modak *et al.* disclosure. For example, it would have been obvious to formulate a composition comprising two or more organic zinc salts (as disclosed in Modak *et al.*) in the instantly claimed emollients, thickeners, etc. Further, it is not inventive to discover the optimum ranges of excipients through routine experimentation. As such, the instantly claimed ranges would have been *prima facie* obvious.

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dodd *et al.* (U.S. Patent No. 6,344,218; Issued Feb. 5, 2002; Filed May 27, 1999) (cited *supra*).

Dodd *et al.* disclose as applied to claims 1-13 and 15-16, *supra*. To summarize, the reference discloses odor-controlling compositions comprising an effective amount of an odor controlling agent, from 40% to 99% of an alcohol antiseptic, from 0 to 10% of a water-soluble metallic salt, from 0 to 10% of a thickener, from 0 to 10% of an emollient, from 0 to 1% of perfume and water (col. 2, lines 24-33). Water-soluble metallic salts are taught to be useful as odor controlling agents (col. 3, lines 45-46). Specifically, preferred metallic salts include zinc gluconate, zinc lactate and zinc salicylate (col. 6, lines 10-12). The metallic salts are present in the compositions in amounts ranging from 0.01% to 10%, preferably 0.3% to 5% (*id.* at lines 17-25).

The instantly claimed thickeners, emollients, surfactants, antioxidants, etc., as well as the instantly claimed ranges, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. As noted *supra*, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In

this case, Dodd *et al.* disclose the general conditions of an odor-controlling composition comprising organic zinc salts. As such, it is not inventive to pick and choose specific excipients and specific concentrations from the Dodd *et al.* disclosure. The reference clearly suggests that odor-controlling compositions could be made from organic zinc salts in combination with various thickeners, emollients, emulsifying agents, etc. As discussed *supra* discovering the optimal concentrations and excipients through routine experimentation is not inventive over the prior art.

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sine *et al.* (U.S. Patent No. 6,183,766; Issued Feb. 6, 2001; Filed May 27, 1999) (newly cited art) in view of Modak *et al.* (U.S. Patent No. 5,965,610; Issued Oct. 12, 1999) (cited by Applicants in IDS filed 11/5/2004).

Sine *et al.* disclose compositions for sanitizing and moisturizing skin surfaces (Abstract). Said compositions comprise: a) 40 to 99% alcohol antiseptic; b) 0.1 to 20% lipophilic skin moisturizing agent; c) degreasing agent; d) 0 to 10% thickener; e) 0 to 15% humectant; f) 0 to 15% perfume; and g) 0 to 60% water (col. 1, line 60 to col. 2, line 16). The alcohol antiseptic is preferably ethanol, thus teaching the alcohol recited in instant claim 1 (col. 2, lines 50-57). The lipophilic skin-moisturizing agent includes hydrocarbon oils and waxes, silicones, fatty acid derivatives, cholesterol, di- and tri-glycerides and vegetable oils (col. 3, lines 9-31). These agents encompass the emollients recited in instant claim 5. Thickening agents include petrolatum (recited as an emollient in instant claim 5) (col. 4, line 42). Degreasing agents include silicones and wax materials (*e.g.*, fluid silicones, polyalkylsiloxanes and cyclomethicone

and dimethicone cross polymer blends) in amounts of 0.01 to 10% (col. 5, line 1 to col. 6, line 63). The silicones and concentrations of silicones encompass those recited in instant claims 8 and 9. Wax materials include dimethicone copolyols, recited as a silicone polymer in instant claim 9 (col. 7, lines 8-24). Optionally, but preferably, the skin moisturizing compositions contain a metallic salt, preferably a water-soluble zinc salt (col. 10, lines 4-6). Said water-soluble zinc salts include zinc gluconate, zinc lactate and zinc salicylate in amounts ranging from 0.1 to 10%, preferably 0.3 to 5% (col. 10, lines 24-40). Mixtures (*i.e.*, "two or more") of the metallic salts can also be used (*id.*). Humectants, including propylene glycol and glycerin (as recited in instant claim 5), may also be used in the compositions (col. 11, lines 36-46). Antimicrobial agents may also be present in the disclosed compositions (col. 12, lines 5-7). Said antimicrobial agents, present in amounts ranging from 0.001 to 5%, include essential oils (e.g., lemongrass oil) and benzalkonium chlorides (col. 12, lines 37-59). The compositions can also contain surfactants and other skin care actives (col. 13, line 60 to col. 15, line 48). Said surfactants and skin care actives include the agents recited in instant claims 12-16.

Modak *et al.* disclose anti-irritant skin compositions (Abstract). Said compositions comprise chlorhexidine salts (col. 5, lines 15-40) and soluble zinc salts, including zinc gluconate, zinc acetate and zinc salicylate (col. 7, lines 5-24). Further, when the composition comprises an anti-microbial agent, the composition may further comprise an anti-microbial synergist, such as benzalkonium chloride or a chlorhexidine salt (col. 9, lines 7-30).

The instantly claimed compositions would have been *prima facie* obvious to one or ordinary skill in the art at the time the invention was made. As noted *supra*, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, Sine *et al.* disclose a skin-moisturizing composition comprising all of the instant claimed components. Modak *et al.* disclose a skin care composition that is useful as an anti-irritant. As such, it would have been obvious to formulate a skin care composition combining zinc salts with the moisturizing components disclosed in Sine *et al.* In fact, Sine *et al.* specifically state that soluble zinc salts can be used to control odor. The fact that the Sine *et al.* did not recognize the anti-irritant effect of organic zinc salts at the time of their invention does not render the instant claims any less obvious. As discussed *supra,* discovering the optimal combination of excipients through routine experimentation is not inventive over the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 5,965,610

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-8 and 11-15 of U.S. Patent No. 5,965,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of the '610 patent claims allows for the presence of other agents, including the antimicrobials and silicone polymers recited in the instant claims. Further, the instantly claimed concentrations are encompassed by the '610 patent claims.

U.S. Patent No. 5,985,918

Claims 1 and 3-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,985,918. The '918 patent claims a topical composition comprising zinc stearate and zinc salicylate in a "topical cream base". Although the conflicting claims are not identical, they are not patentably distinct from each other because the "comprising" language of the '918 patent claims allows for the presence of other agents, including the thickeners, emollients, antimicrobials and silicone polymers recited in the instant claims.

Application No. 10/892,034

Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-14 and 39-42 of copending Application

No. 10/892,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass compositions comprising two or more organic zinc salts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

April 5, 2007

PHYLLIS SPIVACK
PRIMARY EXAMINER